Paper No. 47

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WILLIAM MCBRIDE
and
RICHARD T. DEAN

Appeal No. 2001-0316
Application No. 08/253,973[1]

ON BRIEF

Before McKELVEY, Senior Administrative Patent Judge, and TORCZON and SPIEGEL, Administrative Patent Judges.

SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2 through 8 and 10, which are all of the claims pending in this application. A copy of claim 2, which is illustrative of the subject matter on appeal, is attached to this decision.

[1] Application for patent filed June 3, 1994. According to appellants, this application is a continuation-in-part of application 07/807,062, filed November 27, 1991, now U.S. Patent 5,443,815, issued August 22, 1995; and a continuation-in-part of application 08/095,760, filed July 21, 1993, now U.S. Patent 5,620,675, issued April 15, 1997; and, a continuation-in-part of application 08/092,355, filed July 15, 1993, now U.S. Patent 6,017,509, issued January 25, 2000.

The references relied on by the examiner are:

Fritzberg et al. (Fritzberg)	5,091,514	Feb. 25, 1992
Harris	5,688,485	Nov. 18, 1997

ISSUE

Claims 2 through 8 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harris in view of Fritzberg. We REVERSE.

THE INVENTION

The claims are directed to reagent compositions comprising a targeting moiety covalently bonded to a metal chelator having a defined structure. The targeting moiety is "any compound that binds to or accumulates at a target site in a mammalian body"[2], such as monoclonal antibodies, peptides, receptor binding molecules, adhesion molecules, enzyme substrates, enzyme inhibitors, carbohydrates and oligonucleotides.[3] The chelator is a monoamine, bisamide, monothiol chelator capable of forming a complex with a radioactive metal, e.g., technetium-99m, through the three N atoms provided by the amine and amide groups and the S atom provided by the thiol group,[4] i.e., an NNNS-type chelator. The claimed reagents are complexed with radioisotopes to provide radiopharmaceutical agents for diagnostic and therapeutic applications.[5]

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[2] Specification, p. 22, ll. 6-7.

[3] Specification, p. 19, ll. 5-8.

[4] Specification, formulae VIII, X and XII, pp. 16-18 and p. 21, ll. 2-4.

[5] Specification, p. 21, ll. 18-21).

OPINION

The examiner bears the initial burden of establishing a prima facie case of obviousness. To establish a prima facie case of obviousness, there must be both some suggestion or motivation to modify the reference or combine reference teachings and a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Harris discloses an ester-substituted diaminethiol chelator of the general formula set forth at c. 3, ll. 19-60, i.e., an NNS"Z" chelator, which can be complexed with a radioactive metal to provide a radiopharmaceutical (c. 3, l. 65 - c. 4, l. 39; c. 9, ll. 28-58) useful in radioimaging (c. 4, ll. 52-56). According to the examiner, substituting R_{17}-N-R_{18} for Z (i.e., forming a monoamine), substituting both R_6 together with R_7 and R_{13} together with R_{14} to form oxygens (i.e., forming a bisamide), and substituting the remaining R_1-R_{18} groups with H, alkyl moieties, etc. would yield chelators which differed from the claimed reagents by not including a linker and targeting moiety (answer,[6] p. 3). According to the examiner (answer, p. 4), conjugating a targeting moiety to the chelator of Harris through a linker would have been obvious because Fritzberg describes attaching a target moiety to an NNNS chelator, e.g., a triamide monothiol chelator, complexed with a radioactive metal to deliver the radioactive chelate to a desired site

[6] Paper No. 40, mailed October 13, 1999.

within a mammalian or human host for diagnostic or therapeutic applications (see Fritzberg, Fig. 1 and c. 6, l. 5 - c. 7, l. 10).

However, the examiner has failed to explain where the suggestion or motivation to make these specific substitutions, out of all the possible choices in Harris, can be found in the applied prior art. While we agree with the examiner (answer, pp. 5-6) that Harris' preference for "diaminedithiol chelators" (c. 4, l. 59 - c. 5, l. 7), e.g., the diamidodithiol chelators of Harris' formulae XVII and XIX, is not a teaching away, neither is it a suggestion or motivation to make the specific substitutions selected by the examiner. Therefore, we conclude that the examiner has not established a prima facie case of obviousness over Harris and Fritzberg.

OTHER MATTERS

We note that the oath/declaration is improper because it does not reference parent applications 08/092,355; 08/095,760 or 07/807,062 to which the specification (p. 1) claims priority and fails to acknowledge appellants duty to disclose information known to the person making the oath/declaration to be material to patentablity which became available between the filing date of the prior application and the filing date of the continuation-on-part application. See 37 CFR § 1.63.

We note that appellants have filed a request for interference under 37 CFR § 1.607(a) (Paper No. 46, filed December 13, 1999). Before any further action in this case is taken, the examiner should consider whether interfering subject matter exists between this application and the claims of U.S. Patent No. 5,662,885 and 5,780,006.

CONCLUSION

To summarize, the decision of the examiner to reject claims 2 through 8 and 10 under 35 U.S.C. § 103 over Harris in view of Fritzberg is reversed.

REVERSED

FRED E. McKELVEY
Senior Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

CAROL A. SPIEGEL
Administrative Patent Judge

) BOARD OF PATENT APPEALS AND INTERFERENCES

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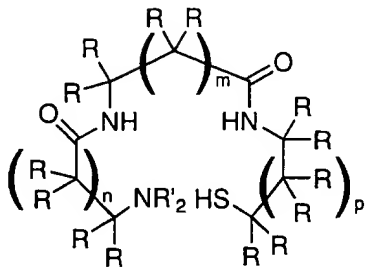
APPENDIX

2. A reagent comprising a targeting moiety covalently linked to a metal chelator having a formula:



wherein:

n, m and p are each independently 0 or 1,

each R′ is independently H, lower alkyl, hydroxyalkyl (C_2-C_4), or alkoxyalkyl (C_2-C_4);

each R is independently H or R", where R" is substituted or unsubstituted lower alkyl or phenyl not comprising a thiol group;

one R or R′ is L, wherein when an R′ is L, -NR′2 is an amine; and

L is a bivalent linking group linking the chelator to the targeting moiety.